REMARKS

The present invention relates to improved methods for inducing protective immunity against *Mycoplasma hyopneumoniae*, specifically employing an inactivated *Mycoplasma hyopneumoniae* bacterin in an amount effective to immunize a recipient animal against infection by *Mycoplasma hyopneumoniae* in a single dose.

The Examiner has required restriction of the Application under 35 USC §121 to one of the following groups: Invention I, Claims 1-9 and 18 drawn to compounds and production; and Invention II, Claims 10-17 drawn to method of use claims.

Applicants elect invention II, as defined by the Examiner, and continue prosecution of Claims 10-17. Applicants reserve the right to file a divisional application directed to the non-elected subject matter.

The Examiner has objected to informalities in the Specification. Specifically, the Examiner objected to the use of trademarked names without capitalization and cites M.P.E.P 608.01 (V) and Appendix 1 as the basis for the objection. The Specification has been further objected to for misspellings of bacteria names on page 3 of the Specification.

As noted in 608.01 (V), quoting form paragraph 6.20, it is proper to "Capitalize each letter of the word in the bracket or include a proper trademark symbol, such as ™ or ® following the word." Therefore, the use of Pluronic® in the application was proper. However, in an effort to respond to each of the objections in the most efficient manner possible, all letters of the cited trademarks have been capitalized. Additionally, the Specification has been amended to correct the spelling of bacteria names. It is believed that the Examiner's objections have been obviated by the foregoing amendments, and accordingly, withdrawal of this objection is respectfully requested.

The Examiner has rejected Claims 10-17 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. It is the examiner's position that the claims spelling errors, improper use of Markush language, fail to define an abbreviated recitation and the language of the claims are vague.

Claims 10-12 and 15-17 have been amended in an effort to obviate the Examiner's rejections. Claim 13 has been canceled without prejudice. Claim 14 is a dependent claim from claim 10, which has been amended as noted above, thus addressing the vagueness or indefiniteness viewed by the Examiner to lie inherently in Claim 14.

The Examiner has rejected Claims 10-17 under 35 U.S.C. § 112, first paragraph, and form 7.31.03, as not being enabled by the Specification.

Applicant respectfully amends and traverses the rejection. Claim 10 has been amended to better claim the invention as provided for in the specification. Specifically, the claim language has been changed from the former language, "an animal", to "a porcine animal." Claim 10 has been further amended by the listing of methods of administering the vaccine in a Markus group. As noted by the Examiner on page 5; the Specification is "enabling for a method for inducing significantly reduced average lung lesions in a porcine animal administered intramuscularly with MHDCE along with Squalane/Pluronic L121 mixture and 2% W/V Carbopol, i.e., test vaccine A, when challenge-infected with 1.0×10^6 *Mycoplasma hyopneumoniae*." Therefore, Claim 10, by recitation of intramuscular administrations in a porcine animal, fully meets the requirements of 35 USC §112 first paragraph. The *George* article cited by examiner demonstrates route-related variation for *Salmonella enteritidis*, the article does not demonstrate the same variation for *Mycoplasma Hyopneumoniae* vaccines. Furthermore, *Fitzgerald et al.*, U.S. Patent No. 5,968,525, demonstrated that *Mycoplasma Hyopneumoniae* vaccines can be effectively administered intramuscularly, subcutaneously, orally and nasally. These administration techniques are explicitly demonstrated at: the paragraph beginning on column 6, line 35; example 4, column 10 line 26; and example 9 column 12, line 20. The *Fitzgerald et al.* patent is in the public domain, therefore, it would be obvious to one skilled in the art that, *Mycoplasma Hyopneumoniae* vaccines may be effectively administered by intramuscular injection, subcutaneous injection, orally and nasally. The amended claims are enabled by the

specification and undue experimentation is not required to practice the invention according to the standard provided by "*In re Wands*" as explained below.

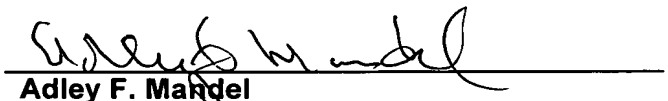
The quantity of experimentation required to effectively perform the invention is minimal for the following reasons; first, the Specification clearly lays out the administration steps necessary for protecting a porcine animal against disease caused by *Mycoplasma hyopneumoniae*. The necessary administration steps are disclosed both in the summary of the invention and in the detailed description of the invention. Additionally, the examples describe specific instances and conditions under which vaccinations have occurred. Second, working examples of the present invention are provided in Examples 1 through 4. Results and statistical data from the Examples are presented in Tables 1 through 5 and the text of the example sections. Particularly, example 1 demonstrated a significant difference between vaccinated subjects and the control, see Tables 1 and 2. Example 2 demonstrated a significant difference, ($p=0.031$), in lung lesion average between the vaccinated group (5.5%) and the control group (10.4%), see the paragraph beginning on line 14 of page 17. Third, the general nature of the instant invention, that being a method of porcine intramuscular vaccination, is well established in the art. Finally, the breadths of amended claims are not overly broad, as the claims apply to methods of intramuscular porcine vaccinations.

Regarding the article authored by *George et al.* and cited by the Examiner as presenting a basis for a 35 USC § 112 rejection, the article presents data showing inconsistent results from vaccinations under a narrow set of conditions. The article pertained to mice inoculated by bacterins of *Salmonella* and *S.enteritidis.* Because porcine animals and mice are different species with different physiological and immunogenic properties; and because *Mycoplasma hyopneumoniae* bacterin is different species with physiological properties different than *Salmonella* and *S.enteritidis* bacterins, it would be improper to extend the limited findings of the George *et al.* article to the information disclosed in the instant invention. There simply are too many differences between the species of animals

and the species of bacteria to properly extrapolate the vaccination irregularities displayed in the George study to the instant invention. This is especially true in light of the statistically relevant data showing efficacy of the instant invention that is presented throughout the Specification. Applicants respectfully traverse the 35 USC § 112 rejection and request withdrawal of the objection and reconsideration and allowance of Claims 10-17 as amended.

By the forgoing amendments and remarks, Applicants believe that the present application is in condition for allowance and respectfully request that the Examiner enter the amendment, reconsider the rejections in light of the remarks herein, and allow the Application. Favorable treatment of the Application is earnestly solicited.

Respectfully submitted,



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